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EXAMINER	
MCKENZIE, THOMAS C	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,794	GERLACH ET AL.	
	Examiner	Art Unit	
	Thomas McKenzie, Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-40* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/5/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to amendments filed on 8/2/05. Applicant has amended claims 20-23, 28, 36, and 40. Claims 1-7 and 9-40 were previously rejected. Claim 8 was designated as containing allowable subject matter.

Response to Amendments and Arguments

2. Applicants' new abstract overcomes the objection made in point #2 of the previous office action. Applicants clarification that claims 20-23 are composition claims overcomes the indefiniteness rejection made in point #3 of that action. Applicants' argument that claim 20 includes compositions of the ten compounds, excluded by proviso from claim 1, is persuasive. Claim 20 is of larger scope that claim 42. Thus, the objection made in point #4 is withdrawn. Applicants' deletion of prevention from the claims overcomes the enablement rejections made in points #7.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-39 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specification does not set forth any steps involved in determining how to identify "a medical condition or illness affected by modulating nucleoside transport proteins, adenosine kinase, adenosine

deaminase, or Al, A2, or A3 receptors". It is unclear what diseases and treatments applicant is intending to encompass. Determining whether a given disease responds or does not respond to such a receptor antagonist and thus, covered by the claim language, will require extensive and potentially inconclusive clinical research. With out such clinical research to identify the patients and diseases Applicants intend to treat, the physician skilled in the clinical arts cannot determine the metes and bounds of the claim. Hence, the claims are indefinite.

Applicants assert that the skilled physician would know the limits of the claim but provide no evidence of that fact. Arguments of counsel alone cannot take the place of evidence. The claim provides for the use of claimed compounds, but the claim does not set forth any steps involved in determining which is "a medical condition or illness affected by modulating nucleoside transport proteins, adenosine kinase, adenosine deaminase, or Al, A2, or A3 receptors".

Suppose that a given drug, which has receptor antagonist properties *in vitro*, when administered to a patient with a certain disease, does not produce a favorable response. One cannot conclude that specific disease does not fall within this claim. Keep in mind that:

A. It may be that the next patient will respond. No pharmaceutical has 100% efficacy. What success rate is required to conclude our drug is a treatment?

Thus, how many patients need to be treated? If "successful treatment" is what is intended, what criterion is to be used? If one person in 10 responds to a given drug, does that mean that the disease is treatable? One in 100? 1,000? 10,000? Will the standard vary depending on the current therapy for the disease?

B. It may be that the wrong dosage or dosage regimen was employed. Drugs with similar chemical structures can have markedly different pharmacokinetics and metabolic fates. It is quite common for pharmaceuticals to work and or be safe at one dosage, but not at another that is significantly higher or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once a day, or four times in divided dosages? The optimum route of administration cannot be predicted in advance. Should our drug be given as a bolus *iv* or in a time-release *po* formulation. Thus, how many dosages and dosage regimens must be tried before one is certain that our drug is not a treatment for this specific disease?

C. It may be that our specific drug, while active *in vitro*, simply is not potent enough or produces such low concentrations in the blood that it is not an effective treatment of the specific disease. Perhaps a structurally related drug is potent enough or produces high enough blood concentrations to treat the disease in question, so that the first drug really does fall within the claim. Thus, how many

different structurally related receptor antagonists must be tried before one concludes that a specific disease does not fall within the claim?

D. Conversely, if the disease responds to our second drug but not to the first, both of which are receptor antagonists *in vitro*, can one really conclude that the disease falls within the claim? It may be that the first compound result is giving the accurate answer, and that the success of second compound arises from some other unknown property that the second drug is capable. It is common for a drug, particularly in the CNS, to work by many mechanisms. The history of psychopharmacology is filled with drugs, which were claimed to be a pure receptor XYX agonist or antagonist, but upon further experimentation shown to affect a variety of biological targets. In fact, the development of a drug for a specific disease and the determination of its biological site of action usually precede linking that site of action with the disease. Thus, when mixed results are obtained, how many more drugs need be tested?

E. Suppose that our drug is an effective treatment of the disease of interest, but only when combined with some very different drug. There are for example, agents in antiviral and anticancer chemotherapy that are not themselves effective, but are effective treatments when the agents are combined with something else.

F. Even the most desired outcome does not unequivocally establish the meaning of the phrase. Our drug alone could be an effective treatment of the disease of interest. One still cannot conclude that the disease cured is a "Factor X mediated disease". What if our drug has a second biological effect in addition to NMDA receptor antagonism? It is possible that this second mechanism is responsible for the positive outcome.

Consequently, determining the true scope of the claim will require potentially inconclusive research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating Alzheimer's disease, does not reasonably provide enablement for treating any of the other claimed diseases. The specification does not enable any physician skilled in the art of medicine, to make the invention commensurate in scope with these claims. The how to make requirement of the enablement statute, when applied to process claims, refers to operability and how to make the claimed process work. "The [eight] factors to be considered [in making an enablement rejection] have been summarized as the

quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. The four main issues are the lack of any correlation between clinical efficacy for disease treatment and Applicants' three *in vitro* assays, the narrow scope of the compounds tested in these assays, the state of the prior art, and the breadth of the claims.

a) Determining if any particular claimed compound would treat any particular "medical condition or illness affected by modulating nucleoside transport proteins, adenosine kinase, adenosine deaminase, or Al, A2, or A3 receptors" would require synthesis of the compound, formulation into a suitable dosage form, and subjecting it clinical trials with a number of fundamentally different CNS diseases described below, or to testing them in an assay known to be correlated to clinical efficacy of such treatment. This is a large quantity of experimentation.

b) The direction concerning treating the claimed diseases is found in lines 2-10, page 9, lines 20-27, page 46, and lines 12-20, page 51, which merely states Applicants' intention to do so. Applicants describe formulations in the passage

spanning line 26, page 51 to line 28, page 54. Doses required to practice their invention are described in the passage spanning line 30, page 54 to line 4, page 55. A 50,000-fold range of doses is recommended. Since NMDA receptor antagonists have only been used to treat Alzheimer's disease, how is the skilled physician to know what dose to use for each of the more than twenty-five unrelated diseases listed in the specification? Is the dose used for Alzheimer's disease to be used for cancer? There is an *in vitro* assay, drawn to binding to the ionotropic NMDA receptor, described in the passage spanning line 25, page 71 to line 19, page 73 with data for only five of Applicants' compounds. Applicants do not state and it is not recognized in the clinical arts this assay is correlated to clinical efficacy for the treatment of any diseases. Applicants state these five compounds are antagonists at this receptor. However, it is not apparent to the Examiner how this was determined since only binding data was obtained. Binding data alone will not distinguish between an agonist and an antagonist at a receptor site.

There is an *in vitro* assay, drawn to inhibition of nucleoside transport protein, described in the passage spanning line 21, page 73 to line 13, page 74 with data for ten of Applicants' compounds. These ten compounds are all different than the five compounds active at the NMDA receptor. Applicants do not state and it is

not recognized in the clinical arts this assay is correlated to clinical efficacy for the treatment of any diseases.

There is an *in vitro* assay, drawn to binding to the purine A_3 receptor, described in the passage spanning line 14, page 74 to line 2, page 75 with data for just a single compound of Applicants'. Applicants do not state and it is not recognized in the clinical arts this assay is correlated to clinical efficacy for the treatment of any diseases. Applicants do not state and it is not apparent to the Examiner if this one compounds is an agonist or an antagonist at this receptor. This lone compound is different than the fifteen compounds discussed above. Applicants do not state and it is not recognized in the clinical arts this assay is correlated to clinical efficacy for the treatment of any diseases.

c) There is no working example of treatment of any disease in man or animals. There is a single working example of a parenteral formulation in lines 4-11, page 75 but no indication of what dose of this formulation is to be used. d) The nature of the invention is clinical treatment of disease with antagonists of the MK801 binding site of the NMDA receptor, which involves physiological activity.

e) The state of the clinical arts in therapy of Alzheimer's disease is that the NMDA receptor antagonist Memantine was approved in Europe for such use in 2002. This evidence is found in paragraph 3, page S47 and paragraph four, page

S48 of Mobius (Int J Geriatr Psychiatry.). The state of the clinical arts in therapy of stroke that the NMDA receptor antagonists CNS 5161 and GV 150526 had not shown clinical efficacy for such use in 2001 or 2002. This evidence is found in the abstract of Lees (Cerebrovas. Dis.) and paragraph two, page 306 and paragraphs five-six, page 311 of Walters (Br J Clin Pharmacol.). Thus, the present claims to treatment of cerebral ischemias and cerebral oedemas lack the required nexus to the assay data in the specification. Additionally, Low (Int J Clin. Pharmacol. Ther.) states in his abstract that neurotoxicity is a common side effect caused by compounds such as Applicants'. This is evidence of the unpredictability in the clinical efficacy of NMDA receptor antagonists such as are present here.

f) The artisan using Applicants invention would be a physician with a MD degree and several years of experience. g) It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 166 USPQ 18, at 24 (In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.), *Nationwide Chemical Corporation, et al. v. Wright, et al.*, 192 USPQ 95 (one skilled in chemical and biological arts cannot always reasonably

predict how different chemical compounds and elements might behave under varying circumstances), *Ex parte Sudilovsky* 21 USPQ2d 1702 (Appellant's invention concerns pharmaceutical activity. Because there is no evidence of record of analogous activity for similar compounds, the art is relatively unpredictable) *In re Wright* 27 USPQ2d 1510 (the physiological activity of RNA viruses was sufficiently unpredictable that success in developing specific avian recombinant virus vaccine was uncertain).

h) The scope of the claims involves all of the thousands of compounds of claim 1 as well as the unknown list of diseases embraced by the phrase "a medical condition or illness affected by modulating nucleoside transport proteins, adenosine kinase, adenosine deaminase, or A1, A2, or A3 receptors", the hundred of diseases embraced by the term "neurodegenerative conditions", and the thousands of different cancers. Thus, the scope of claims is very broad.

MPEP §2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed.

Cir. 1993)." That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

5. Claims 36-39 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pain and Alzheimer's disease, does not reasonably provide enablement for treating every, "a medical condition or illness affected by modulating nucleoside transport proteins, adenosine kinase, adenosine deaminase, or Al, A2, or A3 receptors". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered in making an enablement rejection have been summarized above as have the factors leading to this conclusion.

6. Claim 40 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pain, does not reasonably provide enablement for treating any of the other listed diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered in making an enablement rejection have been summarized above as have the factors leading to this conclusion.

The three disease treatment rejections will be considered together. Applicants make three arguments concerning these rejections. They argue that no reason has been established for doubting the efficacy of their compounds to treat the thousands of different claimed diseases, they point to US Patents 6,071,966 and 6,399,574 for support, and they argue that all compounds that bind to the NMDA receptor are antagonists at that receptor. This is not persuasive.

Firstly, the analysis of the eight Wands points has provided the reason for doubting Applicants assertions. Secondly, the unsubstantiated allegation that all binders to the NMDA receptor are antagonists is not evidence. In fact, Applicants assertion is contrary to the teachings in the elementary textbook Coleman (Medicinal Chemistry: Principles and Practice, Chapter 4). This reference teaches in the second paragraph, page 55, "[a] drawback with ligand binding studies themselves is that it is not always easy to distinguish whether a compound is an agonists or an antagonist, merely that it has an affinity for the receptor/binding site." This is a crucial point for a NMDA agonist, unlike Memantine, would make the symptoms of Alzheimer's disease worse not better. Thirdly, the U.S. Court of Customs and Patent Appeals held, *In re WAITE AND ALLPORT* 77 USPQ 586, "[w]e apprehend that there is no rule of patent law more firmly settled, nor any which has been more frequently stated, than the rule that this court will not allow

rejected claims simply because similar claims may have been allowed by tribunals of the Patent Office in some other application, or even in the particular application under consideration. *In re Lee et al.*, 31 C.C.P.A. (Patents) 768, 139 F.2d 717, 60 USPQ 202, *In re Haller*, 34 C.C.P.A. (Patents) 1003, 161 F.2d 280, 73 USPQ 403."

According to MPEP §2106.02, "it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979)." Applicants have supplied no evidence to support their arguments for enablement.

7. Claims 1-7 and 9-40 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates and

hydrates of the claimed compounds. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with these claims. The factors to be considered in making an enablement rejection] have been summarized above. In the present case the important factors leading to a conclusion of undue experimentation are the absence of any working example of a formed solvate, the lack of predictability in the art, and the broad scope of the claims.

c) There is no working example of any hydrate or solvate formed. The claims are drawn to solvates, yet the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here. There is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

g) The state of the art is that is not predictable whether solvates will form or what their composition will be. In the language of the physical chemist, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometery of the formed solvate, i.e. if one, two, or a half a molecule of solvent added per molecule of host. In the same paragraph on page 365 West (Solid State Chemistry) explains that it is possible to make meta-stable non-equilibrium solvates, further clouding what Applicants mean by the word solvate. Compared with polymorphs, there is an additional degree of freedom to solvates, which means a different solvent or even the moisture of the air that might change the stabile region of the solvate.

h) The breadth of the claims includes all of the hundreds of thousands of compounds of formula IA, IB, and II as well as the presently unknown list of solvents embraced by the term "solvate". Thus, the scope is broad.

Applicants make two arguments concerning this rejection. They argue that alcohols and carboxylic acids, able to form strong hydrogen bonds, are likely to form hydrates and point to Drugs Pharm. Sci. 1999, Vol. 95 as evidence of the routine nature of making solvates. This is not persuasive. Concerning the first point, Applicants claims are not limited to hydrates but includes solvates. A benzene or hexane solvate does not require, in fact will avoid hydrogen bonds. The issue is not the ability of some compounds to form hydrates but which ones, what the composition of those hydrates, and the structure of those hydrates.

Concerning the second point, the book cited has not been provided to the Examiner and is not readily available. Thus, what evidence it contains cannot be evaluated. It is not the Examiners position that no solvates will form from Applicants' compounds. Rather it is his position that it is totally unpredictable which compounds will form solvates, what will be the elemental composition of those solvates, and that the structure of those solvates are beyond the ability of present chemical science to predict. Further evidence of the lack of predictability in the solvate forming arts, cited for rebuttal, is provided by David J.W. Grant (University of Minnesota--Twin Cities Campus College of Pharmacy, Annual Report) who writes, "Crystal Structures and Molecular Simulations Sulfonamides comprise a class of widely used antibacterial drugs. The crystal structures of

various polymorphic phases have been solved and published. However, little work has focused on their solvates. In this laboratory, four sulfonamides (sulfapyridine, sulfadiazine, sulfamerazine, and sulfamethazine) were examined, and over a dozen solvates were discovered. The structures of these solvates are now being determined. The objectives of this study are to probe the intermolecular interactions between the drug and solvent in each solvate and to compare the crystal structures of the solvates with those of the parent drugs and among the solvates themselves. Ultimately, this group is gaining an understanding of how the solvent affects the properties of the drug and the reason behind the formation of each solvate. The researchers are working to predict solvate formation based on the structure of the drug."

The sulfonamide drugs reported above are over fifty years old. Yet in as late as 1999 the synthesis of such solvates was not known even for such a well-studied class of molecules.

Vippagunta (Advanced Drug Delivery Reviews), also cited for rebuttal, states on page 18, section 3.4, "[p]redicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult". "[N]o computer programs

are currently available for predicting the crystal structures of hydrates and solvates".

Allowable Subject Matter

8. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public

PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

11. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.

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